

Unauthorized Remanufactured Instruments Overview

Services Product Marketing

INTUITIVE

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So today's overview is on unauthorized instrument reprogramming

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TRIAL EXHIBIT 560-R

Case No. 3:21-cv-03496-AMO

Date Entered

By

Deputy Clerk

Agenda

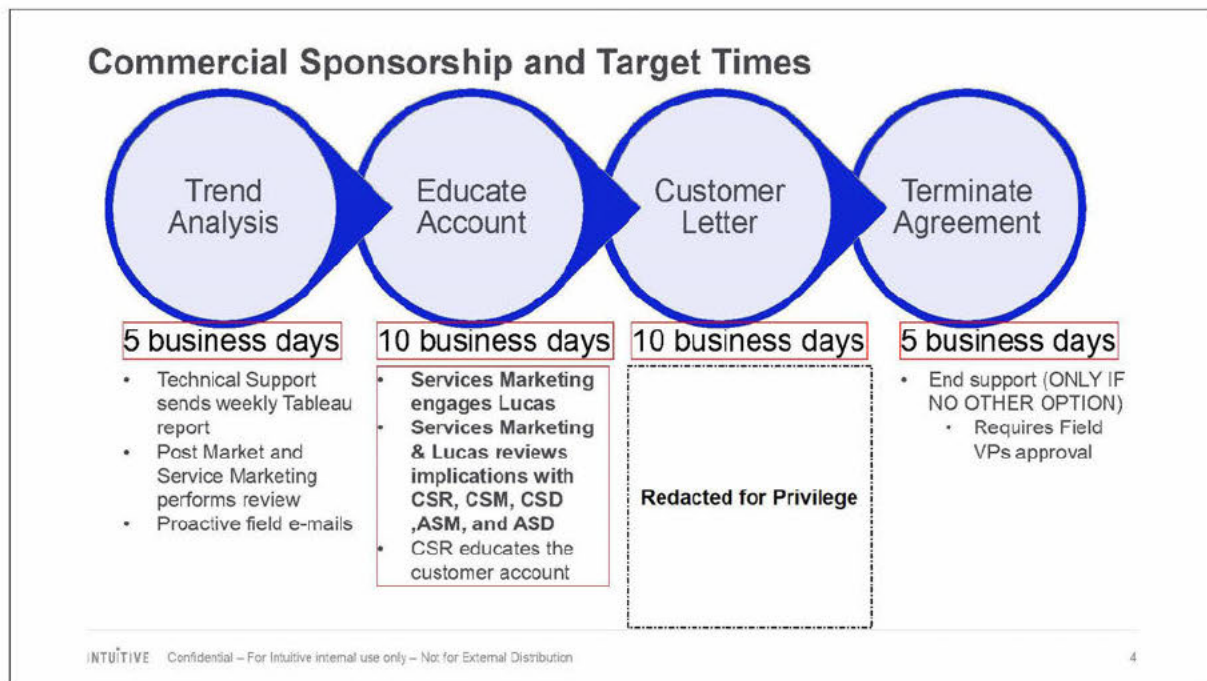
- [Dashboard Review](#)
- Process changes and target metrics
- Review customer accounts at risk
- 3rd party business model changes

Dashboard Summary

- **192** Remanufactured Instrument Uses in **October 2019**
 - Highest use since May 2019
- **49** Instruments were remanufactured in **October 2019**
 - Highest since April 2019
- **19** customer accounts were using remanufactured instruments in **October 2019**
 - 15 of these 19 customer accounts are new users
 - Highest since July 2019

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So what is our process and who is involved?

So first the technical support team sends a weekly tableau report of all remanufactured instruments in the field

The Post Market and Service Marketing teams look through the report and decide whether to monitor the account or to engage the account's sales team

Field teams can reach out to service marketing directly if their customer account is approached by a 3rd party remanufacturer

So if a trend is identified at the account, the Services Marketing team reaches out to the CSR, CSM and ASM to make them aware that their account is using remanufactured instruments and to go through the FAQ together. We ask the CSR to reach out to the account and highlight the following points:

Using remanufactured instruments puts the patient at risk

3rd party manufacturers may not meet the specifications set by Intuitive [REDACTED]

Using remanufactured instruments is a material breach of the SLSA.

Most successful outcomes when administration and surgeons are aligned – these initiatives may stem from other parts of the hospitals – OR Directors, Surgical Services Directors, etc

Redacted for Privilege

The Field Directors are notified accordingly

If the account continues to use remanufactured instruments a final termination notification would be sent to the account and all support at the account would be terminated.

This requires Field Vp approval

Why did we ask for Commercial VP sponsorship?

- Remanufactured instrument resolutions are slower than expected
 - 117 days on average for resolution
 - 4 terminated agreements
 - 3 accounts are at termination risk
- Remanufacturers are gaining traction
 - Booth at ACS
- Legal Outlook

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In the Customer Patient Safety Implications Letter, we say: Intuitive “strongly discourages the procuring of its products through unauthorized channels.”

In the recent letter to Panama City Surgery Center responding to their claim that we condone use of partially used instrument, we wrote: “Customers purchasing and using partially used instruments from other customers or vendors cannot determine how they were handled, or mis-handled, or how well they were processed and sterilized; thus, those instruments could pose risks to patient safety. In addition, third-party transfer of inventory to and between hospitals can prevent tracking and traceability of instruments, which is necessary for safety-related communications with customers. That said, while we discourage the use of any EndoWrist instruments procured from any unauthorized source, our Sales, License and Service Agreement does not prohibit the use of unused and unopened instruments purchased from other sources.

Terminated Accounts and At Risk Accounts

- 3 terminated customer accounts but now under new agreements
 - Conway Regional Medical Center
 - Pacific Coast Surgical Center
 - White County Medical Center
- 1 terminated customer account and new agreement in progress
 - Panama City Surgery
- 3 customer accounts are at risk of termination
 - Genesis Medical Center
 - Pullman Regional Hospital
 - Durango Outpatient Surgery Center

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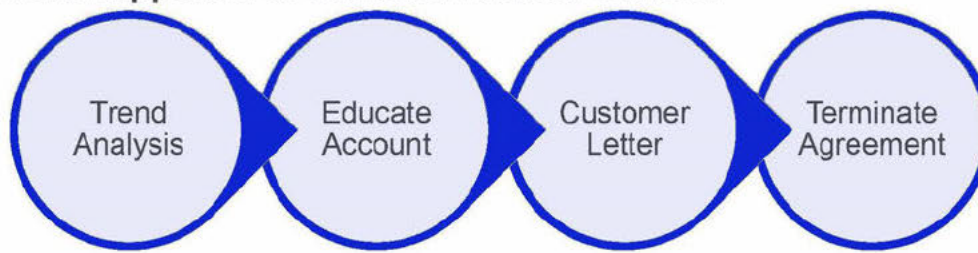
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Genesis Medical Center

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What happened at Genesis Medical Center?



- 1st remanufactured instrument use on **Jun 14th, 2019**
- 20 remanufactured instruments
 - 5 remanufactured twice
- 112 remanufactured instrument uses (post life reset)
- **61** patients operated on with remanufactured instruments
- Onsite conversations with OR Director, CEO and legal team
- Customer influenced by 3rd party marketing collateral
- Letter delivered onsite on **Aug 20th, 2019**
- CSD and FSD working with customer account
- Customer committed to "pausing" remanufactured instrument use
- Termination notice is drafted. Will be sent upon next remanufactured instrument use.

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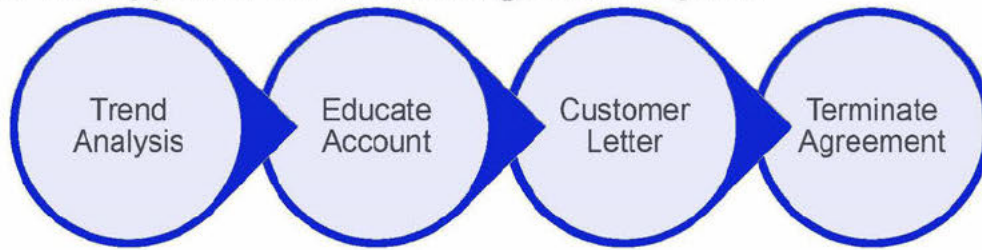
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Pullman Regional Hospital

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What happened at Pullman Regional Hospital?



- 1st remanufactured instrument use on **Jul 24th, 2019**
- Onsite conversations with OR Director, Surgical Services, VP of Surgery
- Customer influenced by 3rd party marketing collateral
- Letter e-mailed on **Sep 12th, 2019**
- CSD and CSR are working to pull instruments out of circulation
- 3 remanufactured instruments
- 14 remanufactured instrument uses (post life reset)
- 12 patients operated on with remanufactured instruments

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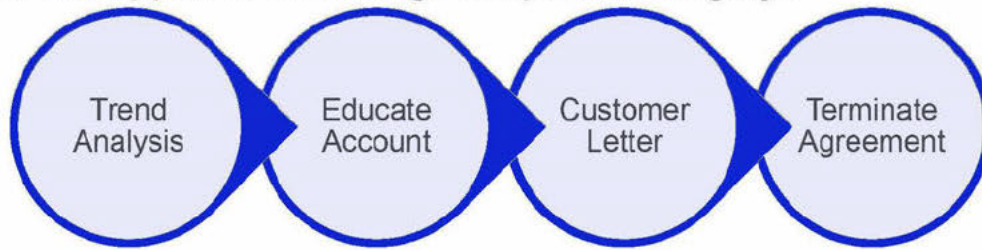
Mention Si to Xi upgrade?

Durango Outpatient Surgery

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What happened at Durango Outpatient Surgery?



- 1st remanufactured instrument use on **Sep 13th, 2019**
 - Phone calls and onsite conversations with Administration
 - Letter e-mailed on **Oct 30th, 2019**
 - KCD and CSR are working to pull instruments out of circulation
-
- 3 remanufactured instruments
 - 14 remanufactured instrument uses (post life reset)
 - 12 patients operated on with remanufactured instruments

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3rd party business model changes

- More aggressive
 - IDNs are "trialing" these instruments
 - Booth at ACS -- 4th gen devices on the table
 - Put flyer photos here

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What's occurring in the field?

- 3rd party companies are remanufacturing da Vinci® Si instruments with additional uses
- Instruments with 1 remaining life are collected-> reprogrammed to 10 lives



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So what's occurring in the field

We have 3rd party companies that are reprogramming our Si instruments with additional uses

Currently we've only seen our Si instruments being reprogrammed

3rd party companies are collecting Si instruments with 1 remaining life and reprogramming them to have 10 lives

Why is this a problem?

- Patient safety risk due to potential instrument degradation
- Accumulated wear and tear and repeated cleaning and sterilization cycles can degrade our instruments
- 3rd party handling and modifications can cause further instrument damage
 - Non-intuitive motion
 - Worn/damaged cables
 - Broken/failed components
- Other potential reprogramming risks
 - Misuse of Intuitive Intellectual Property
 - Reprogramming perceived as Intuitive service
 - Reprogramming may constitute adulteration



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So why is this a problem?

It's a problem because it's a patient safety risk due to potential instrument degradation

Beyond its validated instrument lives, accumulated effects of normal wear and tear plus repeated cleaning and sterilization cycles required between uses will impact the instruments' performance

The reprogrammed instruments can be further damaged because we don't know how these 3rd party companies are handling, transporting, and reprocessing our instruments

These reprogrammed instruments could have potential symptoms of:

Instruments track well with master manipulators, sudden undesired motions or stalls

Worn/damaged cables

Dull or damaged scissor blades

Broken/failed components, could result in fractured components

Besides patient safety, 3rd party reprogramming also puts the company at risk. 3rd party reprogrammers may be misusing intellectual properties that belong to Intuitive. Our customers might start to perceive these 3rd party reprogrammers as part of Intuitive services. 3rd party reprogrammed instruments may be adulterated if they don't abide to the same quality assurance standards that Intuitive abides to.

Sample Customer Letter

- Patient Safety Implications
- Regulatory Implications
- Contractual Implications

Extended Instrument Use Can Impact Product Performance and Patient Safety

All Intuitive products are designed and tested to achieve a targeted level of safety, precision, and dexterity over the programmed number of instrument uses. Gradual degradation of the instrument occurs both from use in surgery as well as repeated cleaning and sterilization cycles required between uses. Examples of degraded performance may include, but are not limited to:

- Unintuitive motion (i.e. instruments do not track well with master manipulators; unexpected motion or stalls);
- Insufficient grip force;
- Dull or damaged scissor blades;
- Worn/damaged cables.

With continued use beyond the instrument's determined useful life, the wear and tear from these additional uses may reduce these levels of safety, precision and dexterity.

In addition, in light of the prescribed cleaning and sterilization processes for the Intuitive instruments, device handling and modification by an outside party that deviates from validated processes submitted and [REDACTED] may cause instrument damage that could create patient safety issue.

Third party remanufacturers or refurbishers may use non validated or incompatible cleaning agents and/or disinfection/sterilization processes, which are likely to damage the instruments, negatively affecting product performance.

Further, third party remanufacturers or refurbishers may damage the instrument's internal mechanisms that interface with the robotic system and allow Intuitive to monitor the device. In sum, the use of third party remanufacturers or refurbishers may affect the operation of the instrument thereby jeopardizing patient safety.

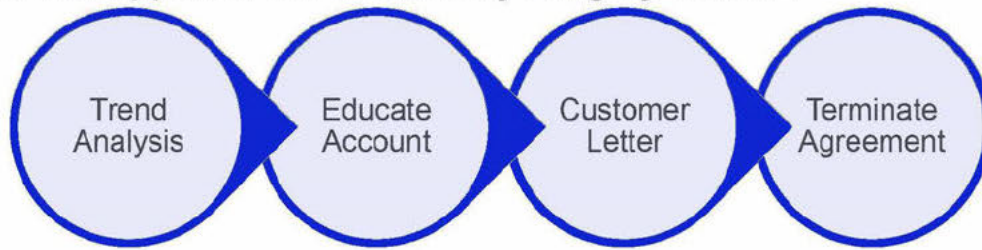
Panama City Surgery Center

Less than optimal outcome

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What happened at Panama City Surgery Center?



- 1st remanufactured instrument use on **Oct 18th, 2018**
- Hurricane Michael influence
- Ongoing CSR conversations with RoCos
- CSR conversations with D. Nursing – **Apr 2019**
- Letter delivered by legal on **Oct 15th, 2019**
- CSR discussion with Administration on **Oct 18th, 2019**
- Termination notice sent **Oct 24th, 2019** – in effect **Oct 28th, 2019**
- Additional letter sent **Oct 28th, 2019**
- New Agreement talks started **Oct 29th, 2019**
- 12 remanufactured instruments
- 72 remanufactured instrument uses (post life reset)
- **65** patients operated on with remanufactured instruments

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Their cavalier attitude towards Intuitive's [REDACTED] quality, and patient safety risk concern.
Their questioning the propriety of Intuitive's patient safety concerns

[REDACTED]

[REDACTED] - insert Intuitive responses here.

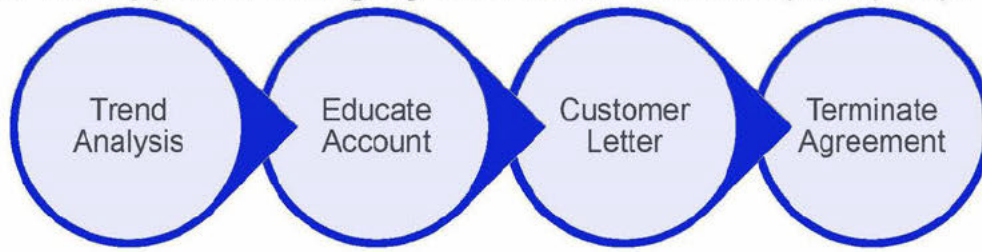
Legacy Good Samaritan

Working together

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What happened at Legacy Good Samaritan Hospital (IDN)?



- 1st remanufactured instrument use on **July 15th, 2019**
- Trend identified on **Aug 28st, 2019**
- ASD reached out to customer account CEO on **Sep 3rd, 2019**
- Last remanufactured instrument use on **Oct 10th, 2019**
- 2 remanufactured instruments
- 14 remanufactured instrument uses (post life reset)
- **14** patients operated on with remanufactured instruments

Next Steps

- Work with your teams to help them understand the situation and its importance to our business
- If you or your team see information from these 3rd party companies such as this invoice, please engage your customers proactively
- Reach out to AJ Inacay for further support (aj.inacay@intusurg.com)
 - Review remanufactured instrument implications in detail
 - Request customer letter

[illegible]

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